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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,541	04/28/2006	Daisuke Matsumoto	10921.403USWO	9838

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EXAMINER	
SCHUBERT, CHRISTOPHER	
ART UNIT	PAPER NUMBER
3734	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,541	MATSUMOTO ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER SCHUBERT	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-333* is/are pending in the application.

4a) Of the above claim(s) *23-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-22,32 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 1, 3-18, and 32-33 are rejected under 35 U.S.C. 102(a) as being anticipated by Koike et al. (WO 03/005907). Cited element numbers and paragraph numbers are based on US Publication (US 2004/0243165) which is the national stage entry.

Regarding claims 1-3, Koike et al. disclose a lancet comprising a lancet body (2A, 2B including stopper 71A,71B) provided with a lancing element (20), and a casing (1A, 1B) including a space (10) extending throughout the casing for retaining the lancet body therein (Fig. 20A and 21), wherein the lancet body is fixed to the casing (in the "wait position") when an external force exceeding a predetermined level in a particular direction is not applied to the casing (paragraphs 81 and 106-110), whereas the lancet body becomes movable relative to the casing when an external force exceeding the predetermined level in the particular direction is applied to the casing (paragraphs 81 and 106-110), wherein the casing has a cross-sectional shape which changes when the external force exceeding the predetermined level in the particular direction is applied to the casing; and wherein the lancet body becomes movable relative to the casing when the cross-sectional shape of the casing is changed. The cross-sectional shape changes

in the sense that movable pieces (70A) are pushed out of the way allowing the stopper (71A) and the lancet body (2A) to move relative to the casing (paragraphs 81 and 106-110; Fig. 19, 20A, 20B, and 21). Koike et al. disclose the particular direction crosses a an axial direction of the casing (since the axial direction is not defined, and any axial direction can be chosen such as one perpendicular to the direction of the force) and the particular direction is directed from an outside of the casing toward an inside of the casing (Fig 11a and 11b annotated below).

FIG. 11A

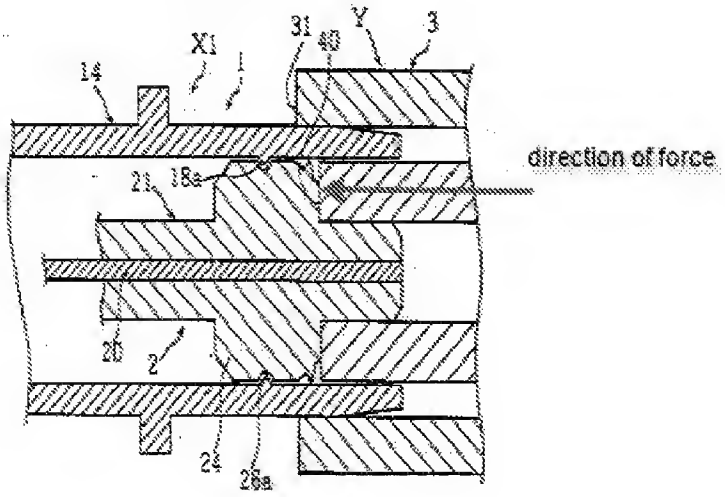
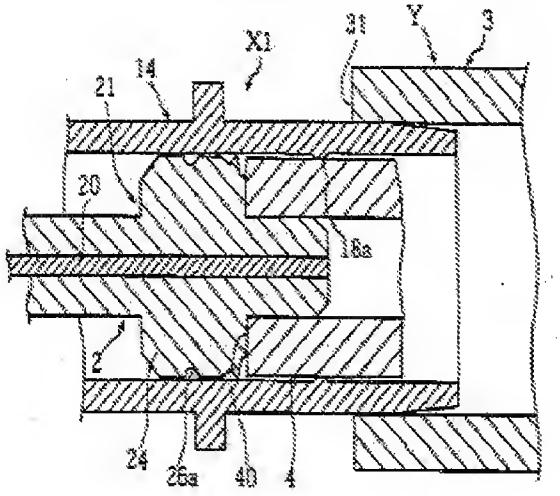


FIG. 11B

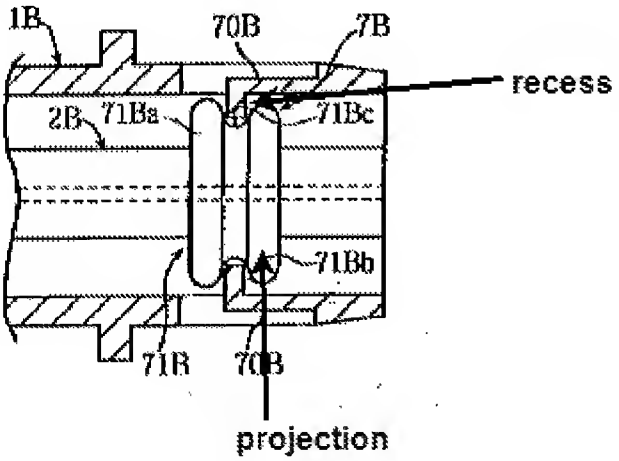


Regarding claim 4, Koike et al. disclose the casing includes a contact portion (70b) which comes into contact with the stopper (71A, 71B) of the lancet body when the external force exceeding the predetermined level in the particular direction is not applied to the casing; and wherein a gap is defined between the contact portion and the lancet body when the cross-sectional shape of the casing is changed. The cross-sectional shape changes in the sense that movable pieces (70A) are pushed out of the way

allowing the stopper (71A) and the lancet body (2A) to move relative to the casing (paragraphs 81 and 106-110; Fig. 19, 20A, 20B, and 21).

Regarding claim 5, Koike et al. disclose the contact portion comprises a projection (70b).

Regarding claim 6, Koike et al. disclose the contact portion comprises a recess (see figure below), and wherein the lancet body is provided with a projection (see figure below) for coming into engagement with the recess (Fig. 21).



Regarding claim 7, Koike et al. disclose an outer diameter of the casing at a portion (14) where the contact portion is not provided is larger than an outer diameter of the casing at a portion where the contact portion is provided (Fig. 10C, 19, 20A).

Regarding claim 8, Koike et al. disclose the casing is formed with a projection (70b) for actively causing the external force in the particular direction to be applied to the casing (Fig. 19, 20A, 20B; paragraphs 81, 106, and 107).

Regarding claims 9, 10, and 33 Koike et al. disclose the casing (1A, 1B) is formed with an opening (70a) for allowing the cross-sectional shape of the casing to

change when the external force in the particular direction is applied, wherein the opening comprises a cutout or a slit (Fig. 19, 20A, and 20B).

Regarding claim 11, Koike et al. disclose after the cross-sectional shape of the casing is changed, the cross-sectional shape returns to an original shape when the application of the external force to the casing in the particular direction is removed (paragraph 107).

Regarding claim 12, Koike et al. disclose a lid (12, 120) for selectively opening or closing an upper opening of the casing (Fig. 2, 8, and 18A-C).

Regarding claim 13, Koike et al. disclose the lid (12, 120) is attached to the casing (Fig. 2, 8, and 18A-C).

Regarding claim 14, Koike et al disclose when the lid (120) closes the upper opening of the casing, the external force exceeding the predetermined level in the particular direction is applied to the casing to change the cross-sectional shape of the casing; and wherein the lancet body becomes movable relative to the casing when the cross-sectional shape of the casing is changed (paragraphs 81 and 106-110; Fig. 19, 20A, 20B, and 21).

Regarding claim 12, 14, and 15, Koike et al. disclose a lid (3,4) for selectively opening and closing an upper opening (proximal opening) of the casing. Koike et al. further disclose when the lid (3,4) closes the upper opening of the casing, the external force exceeding the predetermined level in the particular direction is applied to the casing to change the cross-sectional shape of the casing; and wherein the lancet body becomes movable relative to the casing when the cross-sectional shape of the casing is

changed (paragraphs 81 and 106-110; Fig. 19, 20A, 20B, and 21), the casing is formed with an opening (70a) for allowing the cross-sectional shape of the casing to change when the external force in the particular direction is applied; and wherein the lid includes an operative portion which comes into engagement with the opening and applies the external force in the particular direction to the casing when the lid closes the upper opening. The upper opening is engaged between lid portions (3, 4), wherein lid portion (4) applies the external force to the casing causing movable pieces to move and changing the cross-sectional shape of the casing.

Regarding claim 16, Koike et al. disclose the casing includes a stopper portion (16) for preventing the lancet body from dropping through a lower opening of the casing when the lancet body is movable relative to the casing (paragraph 69).

Regarding claims 17 and 18, Koike et al. disclose a fixer for fixing the lid to the casing when the upper opening is closed by the lid, wherein the fixer comprises a projection (19) provided at one of the lid and the casing, and a hook (29b) provided at the other one of the lid and the casing for engagement with the projection (Fig. 8 and 9A).

Regarding claims 32, Koike et al. disclose a lancet comprising a lancet body (2A, 2B including stopper 71A,71B) provided with a lancing element (20), and a casing (1A, 1B) including a space (10) extending throughout the casing for retaining the lancet body therein (Fig. 20A and 21), wherein the lancet body is fixed to the casing (in the "wait position") when an external force exceeding a predetermined level in a particular

direction is not applied to the casing (paragraphs 81 and 106-110), whereas the lancet body becomes movable relative to the casing when an external force exceeding the predetermined level in the particular direction is applied to the casing (paragraphs 81 and 106-110), wherein the casing is formed with an opening (70A, Fig 19a, b, 20) for allowing a cross-sectional shape to change (when the external force exceeding the predetermined level in the particular direction is applied to the casing); and wherein the lancet body becomes movable relative to the casing when the cross-sectional shape of the casing is changed. The cross-sectional shape changes in the sense that movable pieces (70A) are pushed out of the way allowing the stopper (71A) and the lancet body (2A) to move relative to the casing (paragraphs 81 and 106-110; Fig. 19, 20A, 20B, and 21). Koike et al. disclose the particular direction crosses an axial direction of the casing (since the axial direction is not defined, and any axial direction can be chosen such as one perpendicular to the direction of the force) and the particular direction is directed from an outside of the casing toward an inside of the casing (Fig 11a and 11b annotated below).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koike et al. (WO 03/005907) in view of Nishikawa et al. (US 6, 315,738).

Regarding claim 19, Koike et al. fail to disclose the casing holds an analytical tool for analyzing a particular component contained in body fluid extracted from a lancing target portion. Nishikawa et al. disclose an analytical tool (32), located within the distal end of lancing device, for analyzing a particular component contained in body fluid extracted from a lancing target portion, wherein the analytical tool includes a capillary (33) for moving blood by capillary force, a through-hole for allowing movement of the lancing element, and an introduction port (33a) which communicates with the through-hole for introducing blood to the capillary (Fig. 3 and 4). Nishikawa et al. disclose that providing a detection means such as a test strip within the lancet is advantageous because using one device is more convenient and sanitary than replacing a lancet for a glucose monitoring device (col. 2, ln. 7-12). It would have been obvious to one ordinary skill in the art to modify the casing of the device of Koike et al. to include an analytical tool as taught by Nishikawa et al. in order to provide a more sanitary and convenient technique for testing blood parameters such as glucose levels.

Regarding claim 20, Koike et al. as modified by Nishikawa et al. disclose the analytical tool includes a capillary (33) for moving blood by capillary force, a through-hole for allowing movement of the lancing element, and an introduction port (33a) which communicates with the through-hole for introducing blood to the capillary (Fig. 3 and 4).

5. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koike et al. (WO 03/005907) in view of Moerman et al. (US 7,378,007).

Regarding claim 21, Koike et al. fail to disclose the casing holds an analytical tool for analyzing a particular component contained in body fluid extracted from a lancing target portion. Moerman et al. disclose a lancing device comprising a casing (1) having a lid (3) which holds an analytical tool (32) for analyzing a particular component contained in body fluid extracted from a lancing target portion (Fig. 3A-3C). Moerman et al. disclose that the lancet combined with a detection system in one device simplifies the two step process of piercing the skin and then transferring blood to the detection apparatus (col. 1, ln. 60 - col. 2, ln 5). It would have been obvious to one of ordinary skill in the art to modify the device of Koike et al. to provide a lid as taught by Moerman et al. to be attached after removal of the cap (12, 120) in order to allow the skin to be pierced and blood to be collected for detection by one device.

Regarding claim 22, Koike et al. as modified by Moerman et al. disclose the analytical tool includes a capillary for moving blood by capillary force (col. 6, ln. 1-11), a through-hole (54) for allowing movement of the lancing element, and an introduction port communicating with the through-hole for introducing blood to the capillary (col. 6, ln. 1-11).

Response to Arguments

1. Applicant's arguments filed 10/19/2009 have been fully considered but they are not persuasive.

2. Examiners rejection of claim 1 above with annotated figures 11a-b shows that the force from 40 is directed from the outside of the casing toward an inside of the casing.

3. Furthermore, applicant has amended the claims such that the particular direction of the forces crosses "an axial direction of the casing." Applicant does not define which axial direction the force needs to cross. This broad claim language allows any axial direction to be crossed by the force, such as one directly perpendicular to the application of the force. Examiner upholds the rejection.

Conclusion

4. This is a substitution of applicant's earlier Application No. 10577541. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER SCHUBERT whose telephone number is (571)270-1656. The examiner can normally be reached on M-F 7:30-5pm ESD.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 5712724713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. S./
Examiner, Art Unit 3734

/TODD E. MANAHAN/
Supervisory Patent Examiner, Art Unit 3776